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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,452	09/01/2004	Tadao Ohno	P25874	7197

7055 7590 02/27/2007

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EXAMINER	
WAGHRAY, ANURADHA	
ART UNIT	PAPER NUMBER
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/27/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/27/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/505,452	OHNO ET AL.	
	Examiner	Art Unit	
	Anu Waghray	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/19/05,10/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of certain soluble ingredients from a microorganism as an adjuvant, does not reasonably provide enablement for the use of any soluble ingredient of a microorganism. It is recognized in the art that certain soluble ingredients of a microorganism act as an immunoadjuvant and some do not. Barot-Ciorbaru.et.al. (Int.J.Immunopharmacol. 16(5-6):469-73, 1994) has demonstrated that bacterial extracts are a source of immunostimulating substances, however only certain soluble extracts possess immunomodulatory activity. Further, the immunostimulating extracts differ in solubility and different fractions have different actions on the immune systems. The applicant has not specified the fraction of the soluble ingredient that will function as an immunoadjuvant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno.et.al (CA/2362578 A1) and Ravindernath.et.al. (Pat No: 6218166 B1).

Claims 1-7 and 9-19 are drawn to an immunoadjuvant comprising of a fragment prepared from a solid material selected from a formalin-fixed tissue and/or a cell of an animal including a human wherein a soluble ingredient derived from a microorganism is immobilized to the said fragment. Ohno.et.al (CA/2362578 A1) teaches a tumor vaccine comprising of microparticles prepared from a solidified tumor material selected from a tumor tissue and/or tumor cell and a cytokine (Pg 5). The tumor material is solidified using any fixing agent including formalin (Pg 7). The tumor vaccine also contains an adjuvant, any substance that is known to be effective as an adjuvant including the bacterial derivatives, i.e. soluble ingredient from microorganisms (Pg 9). However, Ohno.et.al do not teach immobilization of the bacteria derived immunoadjuvant on the solidified tumor tissue.

Ravindernath.et.al. (Pat No: 6218166 B1) teaches immobilization of bacteria derived, soluble adjuvant, Monophosphoryl lipid A (MPL) into an intracellular

compartment or to the outer membrane of an intact cell (Pg 3 and 5). The soluble adjuvant (MPL) was immobilized to intact cells (Pgs 4 and 5).

One of ordinary skill in the art at the time the invention was made would have been motivated to immobilize a bacterial adjuvant taught by Ravindernath.et.al. to the formalin fixed tissue taught by Ohno.et.al. with a reasonable expectation of success, because Ravindernath.et.al. teaches that incorporation of bacteria derived, soluble immunoadjuvant elicits immune responses against tumor antigens and prolongs survival and Ohno.et.al's invention taught that the vaccine comprising solidified tumor material is easy to handle and is widely applicable. Therefore it is obvious that combinations of both inventions would be a success.

With respect to claims 8 it is noted that Ohno.et.al. additionally teaches that the vaccine can be administered to the patient from whom the solidified material is derived and to a different patient bearing a tumor that contains the same or relative species of a tumor antigen as contained in the tumor material (Pg,10). Thus it would have been obvious to those of ordinary skill in the art that the composition suggested by the combination of Ohno.et.al and Ravindernath.et.al. could also be administered to such patient population.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5,7 and 9-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,3,6,7 and 17-19 of copending Application No. 09890266 in view of Ohno.et.al and Ravindernath.et.al. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1,3,6,7 and 17-19 of copending Application No. 09890266 are drawn to a vaccine comprising of a fragment of solidified, chemically fixed tumor tissue or cell, at least one cytokine and an adjuvant. The adjuvant is any substance that can induce immune response including a bacteria derived adjuvant such as BCG. The present claims are different from the copending application; in the present application the soluble ingredient (immunoadjuvant) from a microorganism is immobilized to the solidified tumor tissue that is fixed by formalin, while in the copending application the solidified tumor tissue that is fixed with any chemical is mixed with an isolated cytokine and any adjuvant.

However, Ohno.et.al teaches a tumor vaccine comprising of microparticles prepared from a solidified tumor material selected from a tumor tissue and/or tumor cell and a cytokine (Pg 5). The tumor material is solidified using any fixing agent including formalin (Pg 7). The tumor vaccine contains an adjuvant, any substance that is known to be effective as an adjuvant including the bacterial derivatives (Pg 9). Thus it would be obvious to use formalin as a tissue fixative. However, Ohno.et.al do not teach immobilization of the bacteria derived immunoadjuvant on the solidified tumor tissue.

Ravindernath.et.al. teaches immobilization of the soluble, bacterial extract, Monophosphoryl lipid A (MPL) into an intracellular compartment or to the outer membrane of an intact cell (Pg 3). The adjuvant (MPL) was immobilized to intact cell by incubating the cells in an adjuvant-suspended culture media containing adjuvant at higher levels than normal solubility level (Pgs 4 and 5). Therefore, it would be obvious to immobilize the bacterial extract to formalin fixed tumor tissue.

Barot-Ciorbaru.R. (Int.J.Immunopharm.16: 469-473, 1994) and Baker.et.al (Adv.Experimental Medicine and Biology, 319: 31-38, 1992) are cited as of interest for showing that only certain bacterial fractions are source of immunostimulating substances and they differ in their solubility, Baker.et.al. showed that MPL was well known as a soluble ingredient derived from a bacterium.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Waghray whose telephone number is 571-272-

0235. The examiner can normally be reached on Monday-Thursday,7.30AM-5.00PM,Est. alt.Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MARY MOSHER
SUPERVISORY PATENT EXAMINER

1-20-07